REMARKS

Applicants have amended the claims to more clearly define the present invention. The amendment to claim 1, regarding the hydrogel, is supported at page 4, lines 26-31. The amendments to claim 1 regarding the substrate/pregel/web assembly are supported at page 4, lines 1-6. These amendments do not introduce new matter, and their entry is respectfully requested. The amendments to claims 38 and 42 correct minor clerical errors. The amendment to claim 42 regarding the planar nature of the substrate is supported by page 4, lines 12-14. As such, these amendments do not introduce new matter and their entry is respectfully requested.

Claims 1-6, 9-10, 12-15, 17-20, 22, 24-31, 42-43 and 45-46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cheong (U.S. 5,352,508) in view of Jensen (U.S. 5,133,821).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

The present invention is directed to a method for preparing a perforated wound dressing coated with a gel, without substantial occlusion of the perforations. The Examiner admits that Cheong does not teach a coated web. Thus, it cannot teach using a web having a relatively low surface energy on which the gel is applied. The combination of Jensen to Cheong in no way overcomes that deficiency.

Jensen is fundamentally different from both the present invention, and Cheong, because it is directed to applying a gel to a contoured substrate, which presents an entirely different set of challenges as opposed to applying a gel to a perforated substrate. Thus, not only does Jensen not teach coating a perforated substrate, there is nothing in its methods which would suggest it could be adapted to be used to solve that entirely different challenge.

In the method of Cheong, the **perforated** substrate is coated by rollers (column 5, lines 13-17; Examples 5 and 6) or by padding the pregel onto the substrate (Examples 1 to 4). Applicants note that in all of the examples, before the pregel can be cured, the substrate is blown

with air to open up the perforations. Although the Examiner has argued that Cheong makes a general statement that this airblasting is not essential, but "may" be done "if desired" (column 5, lines 17 to 20), in fact every actual example provided in Cheong shows that it was always required, irrespective of the application method. The Examiner has contended that Cheong's teaching indicates that the airblasting step is optional, claiming that "clearly even without this step the majority of the aperatures are unoccluded" (page 4, lines 7-8 of the Office Action). The fact that **every example** of Cheong **uses airblasting** explicitly and clearly teaches the artisan otherwise, that the airblasting step of the Cheong procedure is a required step to achieve a coated substrate without occluded pores. Because the method of Cheong in practice requires air blasting to clear the perforations before curing of the gel, it would not be obvious to the skilled artisan to combine the Jensen method with the Cheong method.

Furthermore, trying to adapt the method of Jensen, directed to **contoured** substrates, to the method of Cheong to coat **perforated** substrates would fail, for the following reasons. As noted by the Examiner, Jensen teaches making a wound dressing by placing a gel between a release paper (i.e. a web) and a substrate, and extruding the gel by a rolling process. Using the web of Jensen with the method of Cheong simply would not work, because the Jensen release paper remains in place until after the gel is cured, thus preventing air blasting as an option for clearing the perforations before curing of the gel. Even assuming arguendo that Cheong does not always require airblasting, it teaches its desirability. Accordingly, since avoiding substantial occlusion of the perforations was a key feature of the Cheong teaching, as was airblasting, it would not have been obvious to the skilled artisan to use a web, which would prevent this desirable airblasting step without offering any obvious alternative way of clearing the perforations.

The combination of Cheong and Jensen also would not be obvious to the skilled artisan because the web of Jensen is applied to a **pre-formed adhesive**, not to a **liquid pre-gel mixture** as claimed in the present invention. Although the Examiner alleged that "Jensen states the silicone paper reduces friction during the process," this is in fact the secondary purpose of the

silicone paper web. The full teaching of Jensen is as follows (column 3, lines 58 to 64; emphasis added):

> "The **thin release web** 40 provides a means for allowing the first major surface 30 of the adhesive layer 26 to be contoured **without** any **transfer of hydrogel** adhesive **to** the first contouring **roller** 48. The thin release web 40 also minimises the friction generated during the contouring of the adhesive 26 by the action of the rollers 50 and 52."

Therefore, the main purpose of Jensen's web is as <u>a thin release sheet to protect the contouring roller from contamination with the adhesive hydrogel</u>. In other words, any reduction of friction achieved as the assembly passes through the contouring rollers is merely incidental, and in no way an intended purpose of the Jensen method.

Jensen's web was never designed or intended to <u>support</u> the hydrogel or a liquid pregel precursor thereof – indeed, Jensen's drawings show the web <u>above</u> the (pre-formed) hydrogel layer, with no possibility of supporting that layer or any liquid precursor thereof.

Furthermore, Jensen never suggested gelling the hydrogel layer *in situ* on the web. The hydrogel layer is supplied ready formed from the left hand side of the drawings, before contact (from above) with the web.

The friction reducing effect of using the thin release web on top of the hydrogel layer relates specifically to Jensen's contouring process. However, contouring is not relevant to the <u>coating of a perforated substrate</u>, with which the present invention and Cheong are concerned. Therefore, it cannot be seen how the reduction of friction that Jensen reports can provide any motivation to use a web in Cheong's process, let alone to use a web in a manner completely different to Jensen's use, i.e. as an <u>underlying support</u> for a liquid pregel which is retained through curing, as opposed to Jensen's use as a thin overlaying release layer and which prevents a key objective of Cheong.

Accordingly, when the combination of Cheong and Jensen are considered, there is nothing to suggest the present invention.

Claims 11, 32-38, and 40-41 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Cheong in view of Jensen in further view of Kundel (U.S. 5,674,346).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

The addition of Kundel does not effect the analysis of the combination of Cheong and Jensen, above, which is incorporated herein. Kundel teaches *in situ* polymerization of multilayer assemblies to prepare a hydrogel/adhesive laminate on a (optionally perforated) substrate, for preparing a bandage. In this case the hydrogel is not adhesive; instead, its main purpose is a water-holding reservoir which contacts a wound and assists healing (column 1, lines 31 to 50).

The problem addressed by Kundel was how to get the hydrogel reservoir to stick better to the substrate (column 3, lines 33 to 45). This shows that the type of hydrogel with which Kundel was concerned were unplasticized, non-adhesive hydrogels for use as water-holding reservoirs. Kundel's solution to this problem was to interpose an adhesive between the hydrogel and the substrate, to use a hydrogel which is copolymerizable with the adhesive (to assist bonding between the hydrogel and the adhesive layers) and to cure the pregel for the hydrogel *in situ* on the adhesive lying on the substrate.

Accordingly, there is no way to adapt the method of Kundel to avoid occlusion of perforations in the substrate by the hydrogel, because the hydrogel is never even in contact with the substrate. It is clear that **Kundel never** sought to **avoid occlusion** of any perforations in the substrate (see, for example, the Figures). Indeed, in the embodiment shown in Figures 4 and 5, the layer assembly is actually assembled before curing in a pressure mold, which serves to force a nylon mesh layer into the hydrogel pregel from the top to embed it there, and also to spread the hydrogel uniformly across the adhesive layer (see column 6, line 48 to column 7, line 3).

It is inconceivable that the addition of Kundel's system to the combination of Cheong and Jensen would be of any relevance at all to a person of ordinary skill in the art seeking to avoid occlusion of perforations of a substrate.

Accordingly, the addition of Kundel in no way overcomes the fundamental deficiency of the combination of Cheong and Jensen.

Claim 1-6, 9-10, 12, 15, 17-20, 24-31, and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over WO 97/42985 in view of Jensen.

Applicants respectfully submit that this rejection should be removed for the following reasons.

WO 97/42985 in no way teaches or suggests using a web with a surface energy lower than the surface energy of the liquid pregel mixture to avoid substantial occlusions in the perforated substrate for the following reasons. The Examiner acknowledges that "WO does not teach the instant web material or instant coating" (OA at page 7). The Examiner then goes on to rely on Jensen to teach the use of a release web with a release coating and showing the use of silicone coated paper.

However, as previously explained, Jensen applies his web to the top surface of a pre-formed adhesive, not to support a liquid pre-gel mixture. Jensen does this to provide a thin release sheet to protect the contouring roller from contamination with the adhesive hydrogel and to reduce friction as the assembly passes through the contouring rollers.

Pressing rollers such as the roller in WO 97/42985 require the correct amount of friction between their roller surface and the material being rolled, in order to operate effectively. If the friction at the axle of the roller (i.e. the friction in the bearings etc.) is too high in comparison with the friction at the roller surface, the material being rolled slips and the roller functions as a fixed rod. The evenness of the rolling immediately suffers adversely. On the other hand, if the friction at the axle of the roller is too low in comparison with the friction at the roller surface, the momentum of the roller can cause it to fail to follow faithfully the inevitable small accelerations and decelerations in the speed with which the material being rolled passes through. Again, the evenness of the rolling will suffer adversely.

Therefore, not only did Jensen not hold out any expectation to the ordinary skilled worker that the system of WO 97/42985 would be improved by replacing the plastic web by a low surface energy web, it did not do anything to overcome the prejudice against an overly friction-free interface nor suggest that such a course of modification would be advantageous for hydrogels, as claimed in the present invention.

WO 97/42985 uses only silicone gels. As shown in Figure 3 and the corresponding description, a layer of uncured gel mixture is placed on a plastic film and the absorbent foam material (containing perforations) is "applied to the layer 9 of uncured gel mixture with the aid of a roller 11" (page 9, lines 8 to 10). The roller applies a pressure force to the foam material as it sits on the uncured gel mixture 9.

Since the gel material is a silicone, there is no risk of undesired sticking to the plastic film, and therefore no need to surface coat the plastic film. Indeed, to surface coat the plastic film with a material that would give the plastic film a lower surface energy than the silicone, uncured gel mixture would be expected to lead to a highly slippery interface between the plastic film and the silicone, uncured gel mixture, which would be unstable as it passed through a roller system and would be unnecessarily and probably problematically friction-free.

In contrast, the present invention is directed to a hydrogel. **Silicone gel** is **not** a **hydrogel.** Additionally, it is hydrophobic, which is entirely different from a hydrogel, which is hydrophillic. Indeed, it is clear that the present invention operates in a markedly different way to the effects produced with the silicone gel in WO 97/42985. In the present invention the liquid pregel mixture **reticulates along the perforated substrate** so that the perforations become free of the pregel, due to the difference in surface energy between the pregel and the web. In contrast, the uncured gel mixture in WO 97/42985 is "drawn by capillary action into those pores or holes in the foam material that open out in that side of the foam material which lies in abutment with the gel mixture" (page 9, lines 18 to 21; emphasis added).

The Examiner has used hindsight reconstruction to combine these references, without providing any basis for why the skilled artisan would be motivated to do so. The multiple

modifications of WO 97/42985 that would be required to arrive at the presently claimed invention (silicone gel → hydrogel; higher surface energy web → lower surface energy web; plastic web → paper, polyester, polyolefin or combination web coated with silicone, polyethylene, polyvinyl fluoride, PTFE or combination; capillary drawing of the uncured gel mixture into the substrate holes → reticulation along the substrate to free the perforations) goes far beyond what could be obvious to one of ordinary skill in the art, and far beyond what is suggested by Jensen.

Accordingly, the combination of the WO 97/42985 and Jensen does not teach or suggest the present invention.

Claim 1-6, 9-10, 12-15, 17-18, 24-31, 42, and 45-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hofeditz (U.S. 4,552,138).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

The present invention teaches methods to coat a perforated substrate, namely a wound dressing, **without substantial occlusion of the perforations**. This is accomplished by first applying **a liquid pregel mixture** using a web, where the web has a surface energy lower than the surface energy of a liquid pregel mixture. The liquid pregel mixture is able to reticulate along the perforated substrate so that perforations become free of it. In contrast, Hofeditz describes applying a gel, not a liquid pregel mixture.

The Examiner acknowledges that Hofeditz does not specify reticulation of the liquid pregel along the perforated substrate (see page 7). However, the differences are substantially greater than that. Namely, it is impossible for the pre-cross-linked gel discussed in Hofeditz to reticulate because it is not a liquid but a gel. Therefore, the gel would spread or laminate the surface – and there is no teaching of preventing such occlusion.

This is clearly seen when one reviews Hofeditz.

Hofeditz discloses applying a 0.5-2mm thick layer of a "pre-crosslinked still moist mass" (i.e. a precipitated curable prepolymer gel) onto siliconized Kraft paper and then "laminating" the "pre-crosslinked still moist mass" with a non-woven fabric or an open-pore foam of polyethylene, polypropylene, polyurethane or polyester and then subjecting the laminate to drying and further crosslinking. See Examples 5-6, which have to be read in combination with Examples 1 and 2 as stated.

In Hofeditz, it is clear that the "pre-crosslinked still moist mass" is not a liquid but a gel. For example, in Example 1 it is stated that "the mass which has precipitated as a gel is then washed thoroughly with hot water" (column 3, lines 35 and 36, emphasis added). Hot water washing would not be possible if the pregel was liquid. Furthermore, the initially precipitated gel is clearly taught to be plasticized by adding glycerol (Example 1) or propane-1,2-diol (Example 2), something that could only be done with a gel, not a liquid (column 3, line 55).

Therefore, as aforesaid, it is impossible for the "pre-crosslinked" gel described in Hofeditz – which will be immobile, unlike a liquid - to reticulate along the perforated substrate so that perforations become free of it. Consistent with this, there is no teaching or suggestion in Hofeditz that such freeing of the perforations is achieved, achievable, intended or desirable.

Thus, for example, claim 7 of Hofeditz, dealing with this lamination embodiment, states as follows (emphasis added):

> "...the gel layer is provided with intermediate and/or covering layers by embedding into the layer of pre-crosslinked gel **spread out, or laminating onto this layer**, a web of woven fabric, non-woven fabric, film or open-pore foam based on a natural substance or a plastic, and then subjecting the laminated product to heat treatment for drying and further lamination."

It is clearly seen that the perforated substrate is either embedded into the spread out layer of pre-crosslinked gel, or laminated onto the spread out layer of pre-crosslinked gel. Either way, no attempt is made to open up the perforations, there would be no expectation that the perforations would remain open, and since the prior art gel is not flowable and mobile like a

liquid there would be no reticulation as is found with a liquid pregel to surprisingly maintain open the perforations in the present invention.

Accordingly, this rejection should be withdrawn.

Claim 11, 19-20, 22, 32-38, and 40-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hofeditz in view of Kundel.

The combination of Kundel to Hofeditz does not make any difference to this analysis. For the reasons set out at page 10 above in the discussion of Kundel, Kundel offered nothing that would suggest to the reader of Hofeditz to replace the gel initially laid down on the siliconized paper with a liquid pregel mixture, in the expectation of gaining the advantages of the present invention.

The problem addressed by Kundel was entirely different to the problem addressed by Hofeditz and the problem addressed by the present invention. Hofeditz was concerned with providing a dressing with an elastic, transparent, water-swellable but water-insoluble, physiologically very well tolerated gel film, which has high mechanical stability and high flexibility both in the dry and in the swollen state (Hofeditz, column 1, lines 35 to 40). Kundel was concerned with the problem of how to get a hydrogel reservoir to stick better to the substrate (Kundel, column 3, lines 33 to 45).

Kundel proposed laying a liquid pregel mixture **down on a preformed substrate/adhesive composite**, the liquid pregel mixture sitting on, and being copolymerized with, the adhesive layer. Since the liquid pregel mixture was **at the top of the structure**, and was anyway not in contact with the substrate, the question of preventing occlusion of the substrate perforations did not arise.

Hofeditz proposed laying a pre-crosslinked gel down on siliconized paper and then applying the substrate on top. The gel pre-crosslinked spread out mass was in that case at the bottom of the structure, but was an immobile gel that could not reticulate along the substrate.

Accordingly, there is nothing in the combination of Hofeditz and Kundel to remotely suggest the present invention without the benefit of impermissible hindsight.

Accordingly, in view of the foregoing, applicants respectfully submit that all claims comply with 35 U.S.C. §103.

Accordingly, applicants respectfully submit that all claims are in condition for allowance. Early and favorable action is requested.

Respectfully submitted,

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